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EXAMINER

KERR, KATHLEEN M

ART UNIT

PAPER NUMBER

1652

DATE MAILED: 06/03/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)
	09/963,790	FARWICK ET AL.
	Examiner	Art Unit
	Kathleen M Kerr	1652

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1) Responsive to communication(s) filed on 18 March 2004.
 2a) This action is **FINAL**. 2b) This action is non-final.
 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4) Claim(s) 5,9-26 and 28-52 is/are pending in the application.
 4a) Of the above claim(s) 10,11,13-26,28 and 29 is/are withdrawn from consideration.
 5) Claim(s) 5,9,12,34,35 and 37 is/are allowed.
 6) Claim(s) 30-32,36,38-43 and 45-52 is/are rejected.
 7) Claim(s) 33 and 44 is/are objected to.
 8) Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9) The specification is objected to by the Examiner.
 10) The drawing(s) filed on _____ is/are: a) accepted or b) objected to by the Examiner.
 Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
 Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
 11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
 a) All b) Some * c) None of:
 1. Certified copies of the priority documents have been received.
 2. Certified copies of the priority documents have been received in Application No. _____.
 3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) Notice of References Cited (PTO-892)
 2) Notice of Draftsperson's Patent Drawing Review (PTO-948)
 3) Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
 Paper No(s)/Mail Date _____

4) Interview Summary (PTO-413)
 Paper No(s)/Mail Date _____

5) Notice of Informal Patent Application (PTO-152)

6) Other: alignment.

DETAILED ACTION

Application Status

1. In response to the previous Office action, a non-final rejection (mailed on December 19, 2003), Applicants filed a response and amendment received on March 18, 2004. Said amendment cancelled Claims 1-4, 6-8, and 27, amended Claims 5 and 9, and added new Claims 30-52. Thus, Claims 5, 9-26, and 28-52 are pending in the instant Office action. Claims 10, 11, 13-26, 28, and 29 remain withdrawn from consideration as non-elected inventions. Claims 5, 9, 12, and 30-52 will be examined herein.

Priority

2. As previously noted, the instant application is granted the benefit of priority for the foreign application 100 47 865.4 filed in Germany on September 27, 2000. Receipt is acknowledged of papers submitted under 35 U.S.C. § 119(a)-(d), which papers have been placed of record in the file. A translation of said priority document has been received.

Maintained – Objections to the Specification

3. Previous objection to the specification for being confusing on page 23, in Example 23, is maintained. Applicant amended paragraph [0077] to clarify the specification; however, said amendment is insufficient. The title of the section still describes “an expression vector”, yet what is described in the following paragraphs is a vector having an internal fragment of the deaD gene for deletion of the endogenous sequence. This example is not about “expression” of the deaD gene in any way. The Examiner suggests removing the word “expression” from paragraph [0077] for clarity.

Withdrawn- Objections to the Specification

4. Previous objection to Abstract is objected to for not completely describing the disclosed subject matter is withdrawn by virtue of Applicant's amendment.
5. Previous objection to the specification for having out-dated application serial numbers is withdrawn by virtue of Applicant's amendment.

Withdrawn - Claim Objections

6. Previous objection to Claims 5 and 9 for depending from rejected claims is withdrawn by virtue of Applicant's amendment rewriting said claims as independent claims.

Withdrawn - Claim Rejections - 35 U.S.C. § 112

7. Previous rejection of Claims 1-4, 6-8, and 27 under 35 U.S.C. § 112, second paragraph, as being indefinite for the phrase "from coryneform bacteria" is withdrawn by virtue of Applicant's amendment canceling said claims.
8. Previous rejection of Claims 1-4, 6-8, and 27 under 35 U.S.C. § 112, second paragraph, as being indefinite for the phrase "codes for the dead gene" is withdrawn by virtue of Applicant's amendment canceling said claims.
9. Previous rejection of Claim 7 under 35 U.S.C. § 112, second paragraph, as being indefinite for the phrase "further comprising ... sense mutations of neutral function" is withdrawn by virtue of Applicant's amendment canceling said claims.

10. Previous rejection of Claims 1-4, 6-8, and 27 under 35 U.S.C. 112, first paragraph, written description, is withdrawn by virtue of Applicant's cancellation of said claims. This rejection is applied to new claims below. Applicant presents no arguments concerning the written description rejection except that the amendment has obviated the rejection. The Examiner disagrees for the reasons point out in the new rejection below.

11. Previous rejection of Claims 1-4, 6-8, and 27 under 35 U.S.C. § 112, first paragraph, scope of enablement, is withdrawn by virtue of Applicant's cancellation of said claims. This rejection is applied to new claims below. Applicant presents no arguments concerning the enablement rejection except that the amendment has obviated the rejection. The Examiner disagrees for the reasons point out in the new rejection below.

12. Previous rejection of Claim 12 under 35 U.S.C. § 112, first paragraph, enabling deposit, is withdrawn by virtue of Applicant's amendment to the specification to include the full address of the depository as well as Applicant's statement of irrevocability in the Remarks presented on March 18, 2004.

Withdrawn - Claim Rejections - 35 U.S.C. § 102

13. Previous rejection of Claims 1-4, 6-8 and 27 under 35 U.S.C. § 102(a) as being anticipated by Nakagawa *et al.* (EP 1108790, published June, 2001) is withdrawn by virtue of Applicant's cancellation of said claims and by virtue of Applicant's filing a certified translation of the priority document DE 10047865.4 (filing date September, 2000).

14. Previous rejection of Claims 1-4, 6-8 and 27 under 35 U.S.C. § 102(e) as being anticipated by Nakagawa *et al.* (USPAP 2002/0197605, filed December, 2000) is withdrawn by virtue of Applicant's cancellation of said claims and by virtue of Applicant's filing a certified translation of the priority document DE 10047865.4 (filing date September, 2000).
15. Previous rejection of Claims 1-3 and 6-8 under 35 U.S.C. § 102(b) as being anticipated by Cole *et al.* (GenBank Accession Z77137) is withdrawn by virtue of Applicant's cancellation of said claims.

NEW ISSUES

Claim Objections

16. Claim 33 is objected to under 37 C.F.R. § 1.75 as being a substantial duplicate of Claim 9. The added limitation of functionality in Claim 33 is inherent in the specific structure of Claim 9. When two claims in an application are duplicates or else are so close in content that they both cover the same thing, despite a slight difference in wording, it is proper after allowing one claim to object to the other as being a substantial duplicate of the allowed claim. See M.P.E.P. § 706.03(k).
17. Claim 44 is objected to as depending from a rejected claim.

Claim Rejections - 35 U.S.C. § 112

The following is a quotation of the second paragraph of 35 U.S.C. § 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

18. Claims 36, 38 and 49-50 are rejected under 35 U.S.C. § 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which

applicant regards as the invention. The “stringent conditions” for the hybridization in Claim 36 with respect to SEQ ID NO:1 are unclear and, thus, cannot clearly define the scope of the polynucleotide of Claim 36. While wash condition temperature is useful in defining which sequence will hybridize and which will not, the buffer, particularly the salt concentration, used is also critical in defining the metes and bounds of a hybridization-type claim. Typically, a combination of lower salt concentration and higher temperatures define stringent conditions, but just how stringent based on the disclosure is unclear. While the specification discusses possible buffer conditions for hybridization, no definite conditions are defined. Thus, Claims 36 and claims depending therefrom are unclear as to their metes and bounds. Clarification is required.

19. Claims 39-43 and 46-48 are rejected under 35 U.S.C. § 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. The phrase “**consisting of at least 18 consecutive nucleotides**” (emphasis added) and related phrases are unclear as to whether the language is open or closed. At their broadest (see M.P.E.P. § 2111), the claims can be interpreted as ---consisting of at least 18 consecutive nucleotides--- *attached to anything else*, which is the essence of “comprising”. At their most limited, the claims might encompass ---consisting of a DNA fragment of SEQ ID NO:1 wherein said fragment consists of at least 18 consecutive nucleotides--- which language limits to fragments of SEQ ID NO:1 from 18 nucleotides to 2381nucleotides (the full-length) and nothing else. In view of the dual interpretation of the claims, clarification is required. If the closed interpretation is intended, the Examiner suggests the latter language.

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20. Claims 39, 40, 43, 45-48, 51, and 52 are rejected under 35 U.S.C. § 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. In Claims 39, 45, and 47, it is unclear if the claimed polynucleotide consists of (a) at least 18 consecutive nucleotides of SEQ ID NO:1 or (b) the complete complement of SEQ ID NO:1 ... or if the claimed polynucleotide consists of (i) at least 18 consecutive nucleotides of SEQ ID NO:1 or (ii) *at least 18 consecutive nucleotides of* the complete complement of SEQ ID NO:1. If the latter is intended, the Examiner suggests using itemization for clarity. Clarification is required.

21. Claims 41-42 are rejected under 35 U.S.C. § 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. The dependency on Claim 30 is wholly unclear if Claim 41 intends to further limit the scope of its parent claim. Claim 30 is drawn to a polynucleotide at least 90% identical to SEQ ID NO:1 and Claim 41 attempts to further limit “said polynucleotide” to “consist of at least 18 consecutive nucleotides”. Does any polynucleotide consisting of at least 18 consecutive nucleotides that are at least 90% identical read on Claim 41? Moreover, Claim 30 has a functional limitation; is a polynucleotide fragment of 18 consecutive nucleotides intended to encode a function protein? The subject matter encompassed by Claims 41-42 is wholly unclear. Clarification is required.

22. Claims 45-48 are rejected under 35 U.S.C. § 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. In line 2 of Claims 45 and 47, the combination of open, “comprising”,

and closed, "consisting of", language is confusing. Is the claim intended to be open or closed with respect to the nucleotide sequence (primer or probe) claimed? Moreover, is the proposed use in the preamble intended to limit the function of the claimed primer or probe. Clarification is required. For purposes of prosecution, the instant claims will be read as wholly open and without functional limitation.

The following is a quotation of the first paragraph of 35 U.S.C. § 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

23. Claim 49 is rejected under 35 U.S.C. § 112, first paragraph, new matter, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. The instant claim is drawn to generic recombinant host cells comprising a polynucleotide having a nucleic acid sequence that encodes a full-length protein; said host cells are not supported by the specification as originally filed. The word "host cell" is not found in the specification. The specification focuses on deleting the disclosed gene endogenous to *C. glutamicum*; no disclosure of a generic expression vector, such as would support a generic host cell, is found. The only support for host cells with a full-length sequence is in the examples wherein a library of *C. glutamicum* genes is made in *E. coli*. Thus, while support can be identified for *E. coli* host cells containing the full-length sequence (claim 50), no support for

other host cells can be found. Applicant must cite clear support from the specification as originally filed or cancel Claim 49.

24. Claims 36, 38-43, and 45-52 are rejected under 35 U.S.C. 112, first paragraph, written description, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. Claim 36 lacks clear structure as noted above for the definition of the hybridization language. Claims 39-41, 45, and 47 contain open language (broadest reasonable interpretation as noted above in rejections under 35 U.S.C. § 112, second paragraph) and are drawn to small fragments of particular sizes without any limitation on function.

The Court of Appeals for the Federal Circuit has recently held that a “written description of an invention involving a chemical genus, like a description of a chemical species, ‘requires a precise definition, such as be structure, formula [or] chemical name,’ of the claimed subject matter sufficient to distinguish it from other materials.” University of California v. Eli Lilly and Co., 1997 U.S. App. LEXIS 18221, at *23, quoting Fiers v. Revel, 25 USPQ2d 1601, 1606 (Fed. Cir. 1993) (bracketed material in original). To fully describe a genus of genetic material, which is a chemical compound, applicants must (1) fully describe at least one species of the claimed genus sufficient to represent said genus whereby a skilled artisan, in view of the prior art, could predict the structure of other species encompassed by the claimed genus and (2) identify the common characteristics of the claimed molecules, e.g., structure, physical and/or chemical characteristics, functional characteristics when coupled with a known or disclosed correlation between function and structure, or a combination of these.

The instant specification discloses polynucleotides encoding polypeptides with at least 70% identity with SEQ ID NO: 2. Applicants have described a genus relating to said SEQ ID NO with both sequence identity limitations and functional limitations (i.e., having DNA/RNA helicase activity). However, the genus of Claim 36 contains polynucleotides within the functional limitations, but without any particular structure (see rejection under 35 U.S.C. § 112, second paragraph above). The genus of Claims 39-42, 43, and 45 contain polynucleotides having limited structural limitations without any particular function wherein the structure cannot support the disclosed function. Thus, the specification has not fully described a genus that lacks either structural or functional limitations so that one of skill in the art would be able to predict other members of the claimed genus.

25. Claims 30-32, 36, 38, 41, 42, 49, and 50 are rejected under 35 U.S.C. § 112, first paragraph, scope of enablement, because the specification, while being enabling for any polynucleotide encoding SEQ ID NO:2 (a deaD gene), does not reasonably provide enablement for polynucleotides encoding polypeptides having as little as 90% identity with SEQ ID NO:2. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make the invention commensurate in scope with these claims. To make the claimed product commensurate with the claimed scope would require undue experimentation.

The factors to be considered in determining whether undue experimentation is required are summarized In re Wands 858 F.2d 731, 8 USPQ2nd 1400 (Fed. Cir, 1988). The Court in Wands states: "Enablement is not precluded by the necessity for some experimentation such as routine screening. However, experimentation needed to practice the invention must not be undue

experimentation. The key word is 'undue,' not 'experimentation.' " (Wands, 8 USPQ2d 1404). Clearly, enablement of a claimed invention cannot be predicated on the basis of quantity of experimentation required to make or use the invention. "Whether undue experimentation is needed is not a single, simple factual determination, but rather is a conclusion reached by weighing many factual considerations." (Wands, 8 USPQ2d 1404). The factors to be considered in determining whether undue experimentation is required include: (1) the quantity of experimentation necessary, (2) the amount or direction or guidance presented, (3) the presence or absence of working examples, (4) the nature of the invention, (5) the state of the prior art, (6) the relative skill of those in the art, (7) the predictability or unpredictability of the art, and (8) the breadth of the claims. While all of these factors are considered, a sufficient amount for a *prima facie* case is discussed below.

The instant specification teaches SEQ ID NO:2, a DNA/RNA helicase, deaD, from *C. glutamicum*, and SEQ ID NO:1, a *C. glutamicum* gene exactly encoding SEQ ID NO:2. The art fully enables any DNA encoding SEQ ID NO:2 based on the degeneracy of the genetic code. While the instant specification describes and enables means for identifying other deaD genes using hybridization methods, etc., these methods do not enable one of skill in the art to make all, or a relevant portion of, the polynucleotide products within the scope of the claims because the ability to find a deaD gene, which is structurally related to SEQ ID NOs:1 and/or 2, is not equivalent to the ability to make a deaD gene as required by the statute (i.e., "make and use"). No description in the specification or the art provides particular residues whose encoding is important within the disclosed sequence so that its deaD-nature is maintained. Thus, one of skill in the art would be unable to predict the structure of the other members of the genus in order to

make such members. Therefore, the instant claims are not enabled to the full extent of their scope.

26. Claims 39-48 and 51-52 are rejected under 35 U.S.C. § 112, first paragraph, scope of enablement, because the specification, while being enabling for full-length SEQ ID NO:1 and polynucleotides consisting of fragments of SEQ ID NO:1, does not reasonably provide enablement for polynucleotides *comprising* fragments of SEQ ID NO:1. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to use the invention commensurate in scope with these claims. To make the claimed product commensurate with the claimed scope would require undue experimentation.

The factors to be considered in determining whether undue experimentation is required are summarized above.

The instant specification teaches SEQ ID NO:2, a DNA/RNA helicase, deaD, from *C. glutamicum*, and SEQ ID NO:1, a *C. glutamicum* gene exactly encoding SEQ ID NO:2. The art fully enables how to use any fragments of DNA encoding SEQ ID NO:1 as probes and/or primers. However, due to the open language of the instant claims, any amount of additional nucleic acid can be added on to the ends of the fragment. Wherein a significant portion of nucleic acid (for example, 10x the fragment size) is added onto the 18 or more nucleotides of SEQ ID NO:1, the nucleic acid as a whole will fail to function as a probe for sequences related to SEQ ID NO:1. In the absence of its functioning as a probe or primer, one of skill in the art would be unable to know how to use the claimed invention. No working examples or description of using such unrelated sequences is found in the specification. The nature of polynucleotides is

that they encode proteins and no proteins that could be primed by the scope of the instant claims has been described so as to enable its use except for SEQ ID NO:2 and homologues thereof. Moreover, the uses of such probes and primers that lack significant homology over the full length of their sequence to SEQ ID NO:1 are wholly unpredictable. Therefore, the instant claims are not enabled to the full extent of their scope. The Examiner suggests closed language for use in probe/primer claims and the like.

Claim Rejections - 35 U.S.C. § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. § 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

27. Claims 32, 39, 41, 43, 45, 47, 49, 51, and 52 are rejected under 35 U.S.C. § 102(a) as being anticipated by Nakagawa *et al.* (EP 1108790, published January, 2001, see IDS). The instant claims are drawn to polynucleotides similar to (being 99% identical to or having at least 18 consecutive nucleotides of) SEQ ID NO:1 and *C. glutamicum* that overexpress the dead gene. The Examiner notes that 99% identical to SEQ ID NO:1 and fragments of 18 consecutive nucleotides of SEQ ID NO:1 do not have support in the priority documents and, thus, are

afforded an earliest effective filing date of September 26, 2001 (the filing date of the instant application).

Nakagawa *et al.* (EP) teach SEQ ID NO:7062, a portion of which (310000-312380 bp) is virtually identical to SEQ ID NO:1 (1-2381 bp), except for two point mutations that result in a single amino acid change in the translated protein (see previously attached alignment).

Nakagawa *et al.* (EP) teach this portion of SEQ ID NO:1 as homologous to DEAD box ATP-dependent RNA helicase deaD (see page 103). Nakagawa *et al.* (EP) also teach overexpression of the disclosed sequences in *C. glutamicum* to produce the encoded polypeptides (see page 22).

28. Claims 32, 39, 41, 43, 45, 47, 49, 51, and 52 are rejected under 35 U.S.C. § 102(e) as being anticipated by Nakagawa *et al.* (USPAP 2002/0197605, filed December, 2000, see previously attached PTO-892). The instant claims are drawn to polynucleotides similar to (being at least 99% identical or having at least 18 consecutive nucleotides of) SEQ ID NO:1 and *C. glutamicum* that overexpress the deaD gene. The Examiner notes that 99% identical to SEQ ID NO:1 and fragments of 18 consecutive nucleotides of SEQ ID NO:1 do not have support in the priority documents and, thus, are afforded an earliest effective filing date of September 26, 2001 (the filing date of the instant application).

Nakagawa *et al.* (USPAP) teach SEQ ID NO:1, a portion of which (1210000-1212380 bp) is virtually identical to SEQ ID NO:1 (1-2381 bp), except for two point mutations that result in a single amino acid change in the translated protein (see previously attached alignment for Nakagawa *et al.* (EP)). Nakagawa *et al.* (USPAP) teach this portion of SEQ ID NO:1 as homologous to DEAD box ATP-dependent RNA helicase deaD (see page 68). Nakagawa *et al.*

(USPAP) also teach overexpression of the disclosed sequences in *C. glutamicum* to produce the encoded polypeptides (see page 18).

29. Claims 39-43, 45-48, and 51 are rejected under 35 U.S.C. § 102(e) as being anticipated by Leach *et al.* (WO 01/90366, filed May, 2001 with priority to May, 2000, see attached PTO-892). The instant claims are drawn to polynucleotides comprising fragments of SEQ ID NO:1 of at least 20 consecutive nucleotides (see broadest reasonable interpretation noted above), vectors, and *E. coli* host cells thereof.

Leach *et al.* teach a 198 base pair nucleotide sequence, SEQ ID NO:6929, described as a "helicase-like ORF"; said sequence at bases 37-58 is identical to SEQ ID NO:1 from 1210-1231, a 22-mer match (see attached alignment). Leach *et al.* also teach using their polynucleotides as probes, primers for PCR, and in vectors and *E. coli* host cells (see pages 13-14 and 37-38).

Examiner's Comment

30. While the claim language of vectors and host cells comprising polynucleotide fragments of SEQ ID NO:1 (Claims 43 and 51-52), wherein said fragments are suitable as probes and/or primers, is clear (no rejection under 35 U.S.C. § 112, second paragraph), the Examiner draws Applicant's attention to said claims because probes and primers are not typically used in vectors and host cells in the art. Perhaps Claims 43 and 51-52 are the result of a typographical error of claim dependence.

Summary of Pending Issues

31. The following is a summary of the issues pending in the instant application:

- a) The specification stands objected to for being confusing on page 23, in Example 23, for describing an expression vector wherein none is disclosed.
- b) Claim 33 stands objected to under 37 C.F.R. § 1.75 as being a duplicate of Claim 9.
- c) Claim 44 stands objected to a depending from a rejected claim.
- d) Claims 36, 38 and 49-50 stand rejected under 35 U.S.C. § 112, second paragraph, as being indefinite for “stringent conditions”.
- e) Claims 39-43 and 46-48 stand rejected under 35 U.S.C. § 112, second paragraph, as being indefinite for the phrase “consisting of at least 18 consecutive nucleotides”.
- f) Claims 39, 40, 43, 45-48, 51, and 52 stand rejected under 35 U.S.C. § 112, second paragraph, as being indefinite as to whether fragments of the complement are included in the scope of the claim.
- g) Claims 41-42 stand rejected under 35 U.S.C. § 112, second paragraph, as being indefinite for the dependency on Claim 30.
- h) Claims 45-48 stand rejected under 35 U.S.C. § 112, second paragraph, as being indefinite for the open or closed nature of said claims.
- i) Claim 49 stands rejected under 35 U.S.C. § 112, first paragraph, new matter.
- j) Claims 36, 38-43, and 45-52 stand rejected under 35 U.S.C. 112, first paragraph, written description.
- k) Claims 30-32, 36, 38, 41, 42, 49, and 50 stand rejected under 35 U.S.C. § 112, first paragraph, scope of enablement (% identity).
- l) Claims 39-48 and 51-52 stand rejected under 35 U.S.C. § 112, first paragraph, scope of enablement (fragments).
- m) Claims 32, 39, 41, 43, 45, 47, 49, 51, and 52 stand rejected under 35 U.S.C. § 102(a) as being anticipated by Nakagawa *et al.* (EP 1108790).
- n) Claims 32, 39, 41, 43, 45, 47, 49, 51, and 52 stand rejected under 35 U.S.C. § 102(e) as being anticipated by Nakagawa *et al.* (USPAP 2002/0197605).
- o) Claims 39-43, 45-48, and 51 stand rejected under 35 U.S.C. § 102(e) as being anticipated by Leach *et al.* (WO 01/90366).

Allowable Subject Matter

32. As previously noted, the closest prior art to the *C. glutamicum* RNA helicase, deaD, gene claimed in the instant application is that of deaD genes from *M. tuberculosis* and *K. pneumoniae* (see IDS for citations). These DNAs encode proteins that are 52% and 45% identical to SEQ ID NO:2, respectively. Exactly SEQ ID NO:1 (Claims 5, 34, and 35) and any DNA encoding SEQ ID NO:2 (Claim 9) are free of the prior art.

Conclusion

33. Claims 5, 9, 12, 34, 35, 37 are allowed, Claims 33 and 44 are objected to, and Claims 30-32, 36, 38-43, are 45-52 are rejected for the reasons identified in the numbered sections of this Office action. Applicant must respond to the objections/rejections in each of the numbered sections in this Office action to be fully responsive in prosecution.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See M.P.E.P. § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 C.F.R. § 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 C.F.R. § 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Kathleen M Kerr whose telephone number is (571) 272-0931. The examiner can normally be reached on Monday through Friday, from 9:00am to 6pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ponnathupura Achutamurthy can be reached on (571) 272-0928. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



Kathleen M Kerr
Examiner
Art Unit 1652

May 28, 2004

ALIGNMENT

ID ABN78518 standard; cDNA; 198 BP.
XX
AC ABN78518;
XX
DT 08-JUL-2002 (first entry)
XX
DE Human helicase-like ORF3465 cDNA, SEQ ID NO:6929.
XX
KW Human; ORF; open reading frame; ORFX; drug screening; diagnosis;
KW disease monitoring; cytokine; cell proliferation; cell differentiation;
KW immune modulation; haematopoiesis regulation; tissue growth;
KW angiogenesis; activin; inhibin; chemotactic; chemokinetic; haemostatic;
KW thrombolytic; tumour inhibition; bodily characteristic; fertility;
KW behaviour; cancer; proliferative disorder; neurological disorder;
KW cardiovascular disease; immune system disorder; organ transplantation;
KW tissue growth disorder; tissue regeneration disorder; diabetes mellitus;
KW hypothyroidism; cholesterol ester storage disease; infection; vulnerability;
KW vasotropic; antipsoriatic; antidiabetic; cytostatic; nootropic;
KW neuroprotective; antiatherosclerotic; anticoagulant; thrombolytic;
KW cardiant; hypotensive; antithyroid; antiinflammatory; immunomodulator;
KW dermatological; analgesic; virucide; antibacterial; fungicide; gene; ss.
XX
OS Homo sapiens.
XX
PN WO200190366-A2.
XX
PD 29-NOV-2001.
XX
PF 24-MAY-2001; 2001WO-US017076.
XX
PR 24-MAY-2000; 2000US-0206690P.
XX
PA (CURA-) CURAGEN CORP.
XX
PI Leach MD, Shimkets RA;
XX
DR WPI; 2002-106200/14.
DR P-PSDB; ABP34492.
XX
PT Novel human polypeptides and polynucleotides useful for diagnosing,
PT preventing and treating cardiovascular disease, neurodegenerative,
PT hyperproliferative disorders and disorders related to organ
PT transplantation.
XX
PS Claim 1; Page 1978; 2508pp; English.
XX
CC Sequences ABP31028-ABP35561 represent 4534 novel human proteins
CC designated ORF (open reading frame) 1-4534, and sequences ABN75054-
CC ABN79587 represent cDNAs encoding them. The invention also encompasses
CC polypeptides at least 80% identical to the ORF1-ORF4534 (collectively
CC referred to as ORFX) proteins, polynucleotides at least 85% identical to
CC the ORFX nucleic acid sequences, vectors and host cells comprising ORFX
CC polynucleotides, the recombinant production of ORFX proteins, antibodies
CC specific for ORFX proteins, methods of detecting ORFX polynucleotides and
CC polypeptides, methods of screening for modulators of ORFX expression or
CC activity, and methods of screening individuals for a predisposition to an
CC ORFX-associated disorder. The ORFX proteins of the invention have a wide

CC range of biological activities, such as cytokine, cell proliferation,
CC cell differentiation, immune modulation, haematopoiesis regulation,
CC tissue growth, angiogenesis, activin or inhibin activity, chemotactic/
CC chemokinetic activity, haemostatic activity, thrombolytic activity,
CC receptor/ligand, antiinflammatory activity, tumour inhibition activity,
CC and antiinfective activity, and may also be involved in the determination
CC of bodily characteristics, fertility and behaviour. ORFX proteins,
CC nucleic acids and antibodies may be used in the treatment of cancers,
CC other proliferative disorders such as psoriasis and benign tumours,
CC neurological disorders such as epilepsy and Alzheimer's disease,
CC cardiovascular diseases, immune system disorders, disorders related to
CC organ transplantation, disorders of tissue growth and regeneration,
CC diseases such as diabetes mellitus, hypothyroidism, and cholesterol ester
CC storage disease, and infectious diseases caused by viral, bacterial,
CC fungal and other pathogens. ORFX nucleic acids may also be used as a
CC source of primers and probes, in the detection of ORFX genomic sequences
CC or transcripts, in the identification and cloning of homologous
CC sequences, in genetic diagnosis, and in forensic biology. The ORFX
CC nucleic acids may additionally be used to produce transgenic animals
CC which may be useful for studying the function and/or activity of ORFX
CC protein, and in drug screening. The ORFX proteins may also be used as
CC immunogens to generate specific antibodies, which are useful in the
CC diagnosis, treatment and monitoring of ORFX-associated diseases

XX

SQ Sequence 198 BP; 33 A; 78 C; 55 G; 31 T; 0 U; 1 Other;

Query Match 0.9%; Score 22; DB 6; Length 198;
Best Local Similarity 100.0%; Pred. No. 5.5;
Matches 22; Conservative 0; Mismatches 0; Indels 0; Gaps 0;

Qy 1210 GTTCACCGCATTGGCCGCACCG 1231
Db 37 GTTCACCGCATTGGCCGCACCG 58